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# Clinical outcomes of foot and ankle fractures treated with a new type of u-HA/PLLA bone screw

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# Disclosures

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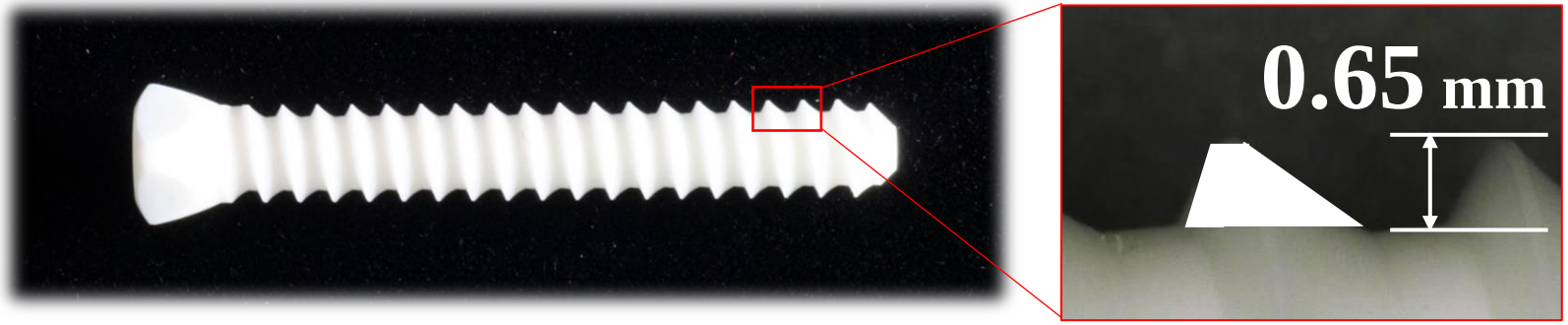
**COI: The screws used in this study were developed by authors S. Imade and Y. Uchio in conjunction with Teijin Medical Technology and Shimane Institute for Industrial Technology.**

**S. Imade and Y. Uchio own the design rights to this screw.**

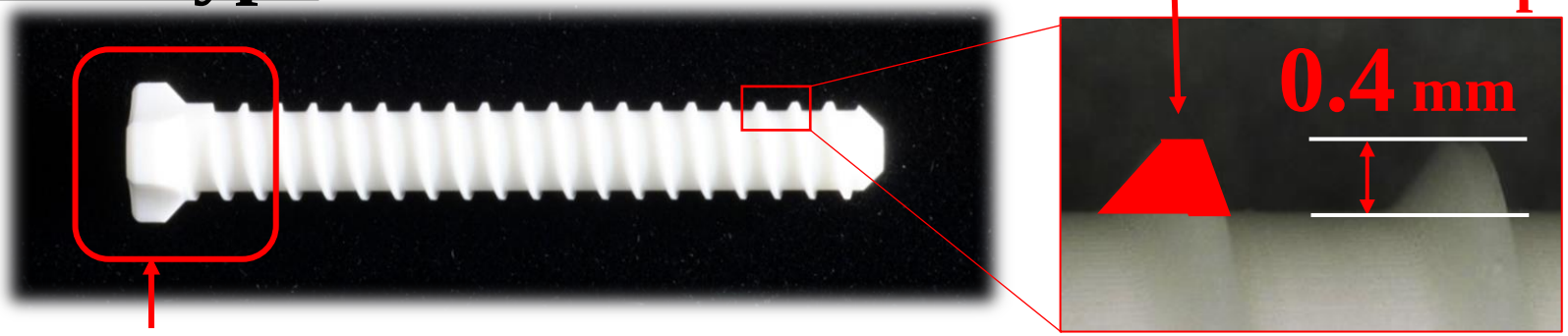
# New u-HA/PLLA* bone screw

## Conventional




| Major dia. (mm) | Minor dia. (mm) | Thread depth (mm) | Pitch (mm) |
|---|---|---|---|
| 4.5 | 3.2 | 0.65 | 1.6 |
| 4.5 | **3.7** | **0.4** | 1.6 |

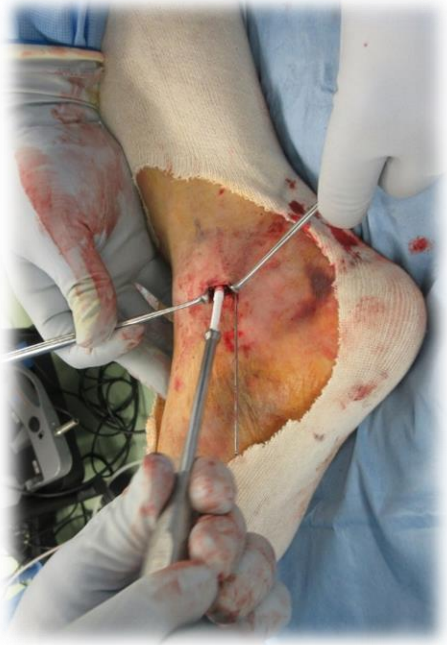
## New type




Thin screw head

Reverse tapered thread

Shallower thread depth



Apply to foot and ankle fractures.

*unsintered-hydroxyapatite/Poly-L-lactide

# Purpose

**This study aims to clarify the clinical outcomes of foot and ankle fractures treated with the new u-HA/PLLA screw.**

# Subjects

**Duration of study: June, 2021 – March, 2022**

**Inclusion criteria:**

- **Foot and ankle fractures treated using the new u-HA/PLLA screw.**
- **Follow-up of more than 6 months after surgery.**

**Exclusion criteria:**

- **Open fractures.**
- **Patients with skin disease around the affected area.**
- **Patients with systemic disease (RA*, DM**, etc.).**

*Rheumatoid arthritis
**Diabetes mellitus

# Assessment

**A. Clinical evaluation**

- **JSSF* ankle/hindfoot scale at final survey** (Niki H, *et al*. J Orthop Sci, 2005)
- **Presence of irritation of surrounding tissue.**

**B. Imaging evaluation**

**X-rays taken at examinations (about once a month).**

**CT performed preoperatively, and postoperatively at 0, 3 and 6 months and at final survey.**

- **Pre- and postoperative immediate distance between bone fragments: CT**
- **Time to bone fusion: X-ray and CT**
- **Presence of screw loosening until final survey: X-ray and CT**
- **Presence of screw breakage until final survey: CT**

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# Results

## 7 patients were selected under the inclusion and exclusion criteria.

| No. | Age (years) | Gender | F/U duration (months) | Time to surgery (days) | Site | Fixed site | Fracture type | Screw number | Duration of immobilization (weeks) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 53 | M | 15 | 11 | Ankle | MM*, PM** | SER (Stage 4) | 3 | 1 |
| 2 | 67 | M | 14.5 | 16 | Ankle | MM, PM | SER (Stage 4) | 4 | 1 |
| 3 | 81 | M | 12 | 8 | Ankle | MM, Synd.*** | PER (Stage 4) | 3 | 4 |
| 4 | 54 | M | 14.5 | 14 | Ankle | PM | SER (Stage 4) | 1 | 1 |
| 5 | 81 | M | 13 | 6 | Ankle | MM, Synd. | PAB (Stage 2) | 3 | 4 |
| 6 | 43 | M | 9 | 9 | Talus | Body | Type 1 | 2 | 4 |
| 7 | 71 | M | 7 | 10 | Talus | Lat. process | - | 1 | 2 |
| Avg. | 64.3 | | 12.1 | 10.6 | | | | 2.4 | 2.4 |

*Medial malleolus; **Posterior malleolus; ***Syndesmosis

| No. | Duration of NWB* (weeks) | Time to FWB** (weeks) | Distance between bone fragments (mm) | | Time to bone fusion (weeks) | Presence of screw failure | | Presence of Irritation of surrounding tissue | JSSF scale at final survey (points) |
|---|---|---|---|---|---|---|---|---|---|
| | | | Pre-OP | Post-OP | | Loosening | Breakage | | |
| 1 | 4 | 8 | 2 , 1 | 0.5 , 0.3 | 20 | - | - | - | 100 |
| 2 | 3.5 | 6.5 | 1.2 , 2.5 | 0.2 , 0.5 | 9 | - | - | - | 100 |
| 3 | 6 | 8 | 2.4 | 0 | 9 | - | - | - | 91 |
| 4 | 2 | 4 | 2.3 | 0.4 | 9 | - | - | - | 85 |
| 5 | 5 | 7 | 1.8 | 1.0 | 13 | - | - | - | 100 |
| 6 | 10 | 16 | 2.9 | 0 | 24 | - | - | - | 82 |
| 7 | 6 | 12 | 1.9 | 0 | 12 | - | - | - | 72 |
| Avg. | 5.2 | 8.8 | 2.0 | 0.3 | 13.7 | | | | 90 |

*p*=0.0004

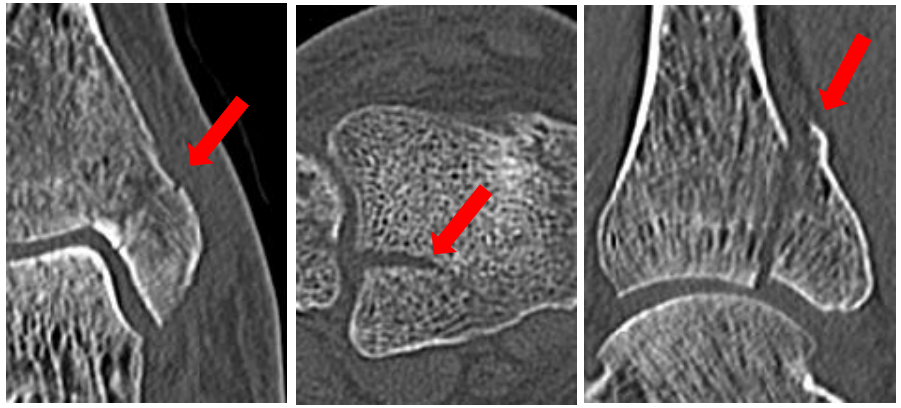
*Non-weight bearing; **Full weight bearing

**Details of JSSF point reduction factors**

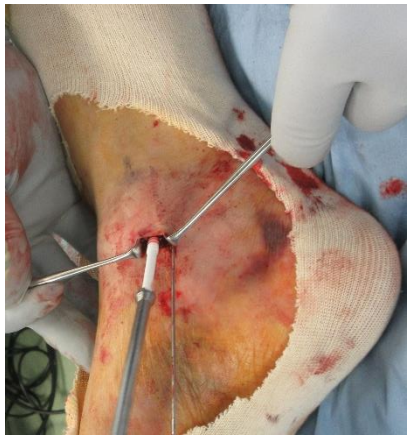
- **Case 3: Restriction of activities due to concomitant disease (drop foot caused by lumbar spinal stenosis).**
- **Case 4: Pain and restriction of activities due to traumatic superficial peroneal nerve injury.**
- **Case 6: Pain and restriction of activities.**
- **Case 7: Pain and restriction of activities.**

# Case report (Case 2)

## Trimalleolar fracture



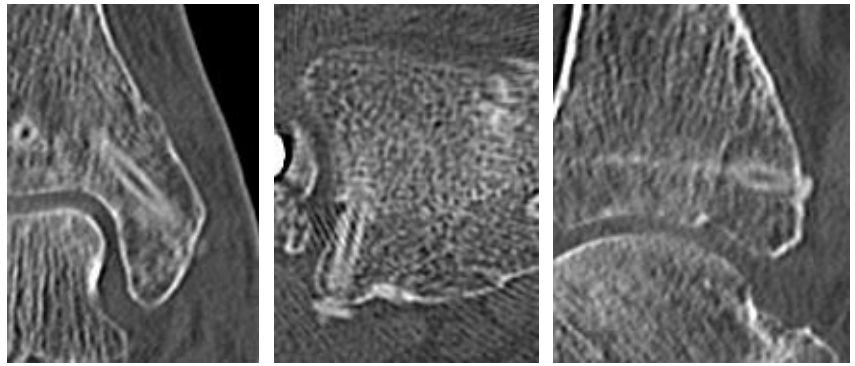
Preoperative images (X-ray, CT)



Fixation of
medial malleolus

Fixation of
posterior malleolus

Immediately after surgery



At 9 weeks after surgery

# Discussion

## Advantages of the conventional u-HA/PLLA screw

### 1. No need for removal

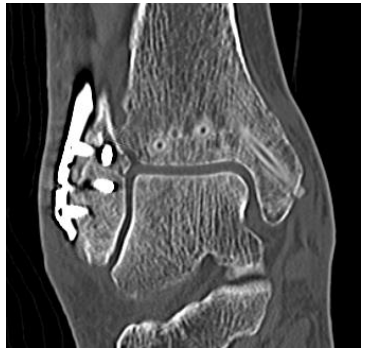
In vivo absorption

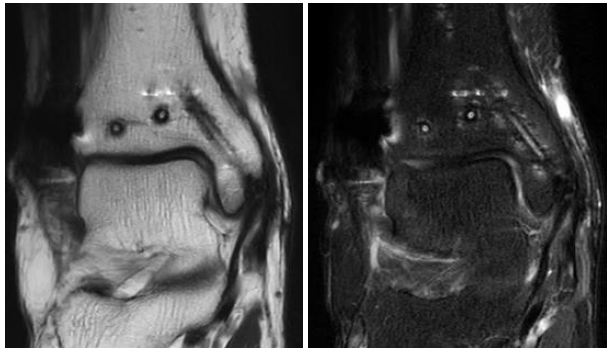
(Shikinami Y, *et al*. Biomaterials, 2005)

### 2. No obstruction for imaging

Facilitates diagnostic imaging because fewer artifacts arise.

(Rendenbach C, *et al*. Dentmaxillocac Radiol, 2018)





## Issues of the conventional u-HA/PLLA screw

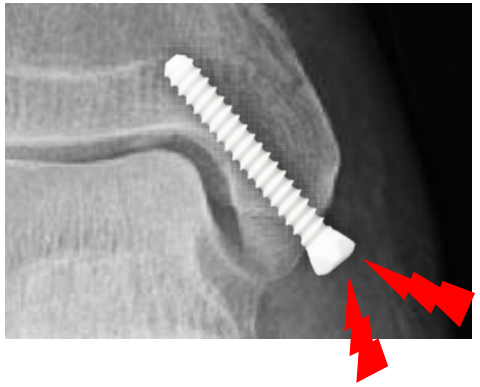
### 1. Fragility

Risk of screw breakage

(Pisecky L, *et al*. EFFORT Open Rev, 2021)

(Lee JS, *et al*. Foot Ankle Surg, 2021)

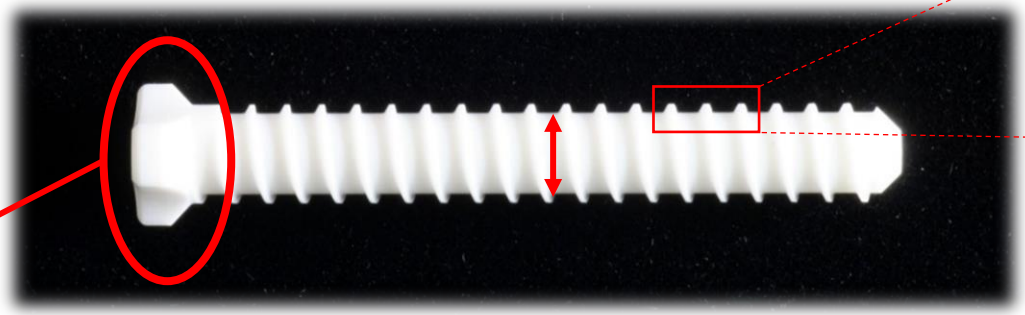
### 2. Irritation of surrounding tissue due to large screw head



# Properties of the new u-HA/PLLA screw

Low irritation
to tissues.

Small screw head

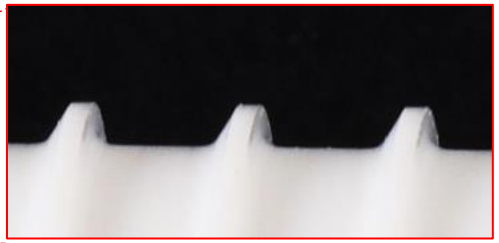


Wide minor diameter

⇩

Improved breakage resistance.

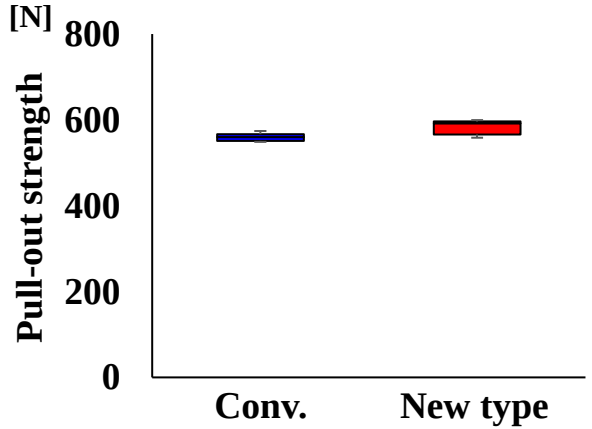
Bending strength: 24%
Shearing strength: 22%
Torsional strength: 27%

Reverse thread

⇩

Pull-out strength maintained.




**Clinically, no problems were caused by the new u-HA/PLLA screw.**

# Conclusion

**In the short term, there were no apparent failures in the clinical use of the new u-HA/PLLA screws for foot and ankle fractures.**

**However, medium- to long-term results and indication criteria are unknown. Continued follow-up is required.**

# References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